

**REMARKS****STATUS OF CLAIMS**

Claims 22-25 and 28-68 are currently under examination. Rejoinder of claims 28, 36, 39-41, 44-45 and 47 is noted with appreciation.

**CLAIM REJECTIONS****Rejections under 35 U.S.C. § 112, first paragraph**

Claim 45 has been rejected as allegedly failing to comply with the written description requirement of 35 U.S.C. § 112. The Examiner's rejection is based on the premise that the structure or amino acid sequence of the immunogen is required. Applicants respectfully disagree.

The term "unidentified" is recited in claim 19 of U.S. Patent No. 6,060,056 which issued on May 9, 2000. Claim 19 recites: "The conjugate of claim 1 wherein the antibody-mediated pathology is an autoimmune disorder and the associated immunogen is unidentified." Currently rejected Claim 45 recites the same language as Claim 19 of U.S. Patent 6,060,056.

Applicants respectfully submit that, as Claim 19 of U.S. Patent 6,060,056 has been issued by the Office, and thus was considered by the Office to be described and enabled, so should claim 45 of the instant application. Accordingly, Applicants respectfully request that the rejection of pending claim 45 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Following the teaching in the specification and claims, one of skill in the art does not need to know what the immunogen is in order to practice the claimed invention. The specification teaches, *inter alia*, how to select analog molecules that bind specifically to antibodies to which the T cell-dependent immunogen binds specifically (see, for example, bridging paragraph between pp. 26-27 and pp. 27-28). Furthermore, the specification also teaches how to select for those analogs that lack T cell epitopes (see, for example, bridging paragraph between pp. 26-27 and pp. 27-28). For example, by following the teaching of the specification, one of skill in the art can start with a

candidate analog, determine if it binds specifically to the relevant antibodies and if so, then determine if it lacks a T cell epitope. If this candidate meets both criteria, then by the definition of “analog” provided in the specification (p. 18, lines 4-7), it is an analog of the immunogen due to a lack of T cell epitopes and binding to antibodies to which the T cell-dependent immunogen binds. Thus, one of skill in the art can select appropriate analog molecules of an immunogen without knowing the identity, such as the structure, of the immunogen. As such, the specification provides written description support for claim 45 and Applicants respectfully request that the rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

Applicants disagree with the Examiner’s characterization of the conjugates disclosed in the instant specification, as set forth on page 3 of the outstanding Office Action. Namely, the Examiner suggests that the instant specification discloses only certain immunogens conjugated via particular functional groups to a valency platform molecule as such as shown on page 31 of the specification. The specification’s teachings are not limited to the conjugates identified by the Examiner. As noted above, the specification teaches how to select analog molecules that bind specifically to antibodies to which the T cell-dependent immunogen binds specifically and how to select for those analogs that lack T cell epitopes. Further, chemically-defined valency platform molecules are taught throughout the specification, and are not limited to the platform molecule depicted on page 31 of the specification. For instance, pages 4-9 and the examples starting on page 30 disclose chemically defined valency platform molecules for use in the claimed invention. The teachings of the specification establish that the inventors, at the time of filing, were in possession of the claimed invention.

For the reasons presented above, Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection of claim 45.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claim 45, reciting an “unidentified immunogen,” has been rejected as allegedly indefinite under 35 U.S.C. §112, second paragraph. Applicants respectfully disagree and seek withdrawal of the present rejection.

Claim 45 is not indefinite because a person of skill in the art would understand what is claimed by claim 45, in light of the specification. As noted above, the specification teaches, *inter alia*, how to select analog molecules that bind specifically to antibodies to which the T cell-dependent immunogen binds specifically (see, for example, bridging paragraph between pp. 26-27 and pp. 27-28) and how to select for those analogs that lack T cell epitopes (see, for example, bridging paragraph between pp. 26-27 and pp. 27-28). When analyzed in light of the application disclosure, claim 45 defines with a reasonable degree of particularity the invention claimed. Accordingly, claim 45 is not indefinite and Applicants respectfully request withdrawal of the present rejection.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 22-25 and 28-68 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,268,454 (“the ‘454 patent”) in view of U.S. Patent No. 5,276,013 (“the ‘013 patent”). Applicants traverse the present rejection on the ground that U.S. Patent Nos. 5,268,454 and 5,276,013 are not available for use in a 35 U.S.C. § 103(a) rejection against the presently pending claims.

The subject matter of the ‘454 patent and the instant application were co-owned or subject to an assignment obligation to the Assignee of record in the instant application at the time the presently claimed invention was made. The ‘454 patent application was filed February 8, 1991 and did not publish until its issue date, December 7, 1993. Accordingly, the ‘454 patent is not available against the instant application under 35 U.S.C. § 102 (a) or (b). Even if the ‘454 patent were to qualify as an available reference under 35 U.S.C. § 102(e), which applicants are not conceding, a reference that is available only under 35 U.S.C. §§ 102 (e), (f) or (g) will not preclude patentability under 35 U.S.C. § 103(a) where the subject matter of the reference and the claimed inventions were

owned by or subject to an obligation of assignment to the same entity at the time the claimed invention was made. 35 U.S.C. § 103(c). Accordingly, a 35 U.S.C. § 103(a) rejection based on the '454 patent is improper and Applicants respectfully request withdrawal of the present rejection.

Similarly, the subject matter of the '013 patent and the instant application were co-owned or subject to an assignment obligation to the Assignee of record in the instant application at the time the presently claimed invention was made. The '013 patent did not publish until its issue date of January 4, 1994. Thus, the '013 patent is not available against the instant application under 35 U.S.C. § 102 (a) or (b). Even if the '013 patent were to qualify as an available reference under 35 U.S.C. § 102(e), which applicants are not conceding, a reference that is available only under 35 U.S.C. §§ 102 (e), (f) or (g) will not preclude patentability under 35 U.S.C. § 103 where the subject matter of the reference and the claimed inventions were owned by or subject to an obligation of assignment to the same entity at the time the claimed invention was made. 35 U.S.C. § 103(c). Accordingly, a 35 U.S.C. § 103(a) rejection based on the '013 patent is improper and Applicants respectfully request withdrawal of the present rejection.

U.S. Patent Nos. 5,268,454 and 5,276,013 are not available for use in a 35 U.S.C. § 103(a) rejection against the presently pending claims, rendering the Examiner's rejection made thereon moot.

### **Obviousness-Type Double Patenting**

Claims 22-25 and 28-68 are rejected under the judicially created doctrine of obviousness-type double patenting in view of claims 1-39 of U.S. Patent No. 6,060,056. Applicants traverse the present rejection for the reasons presented below and respectfully request its withdrawal.

The claims of the '056 patent do not suggest conjugates with the certain structural characteristics recited in the instant claims. In particular, there is no suggestion in the claims of the '056 patent of a conjugate formable by the conjugation of at least two analog molecules to a chemically defined valency platform molecule comprising branching groups, a valency provided by attachment sites located at termini of the valency platform molecule and where the number of

branching groups predetermines the number of attachment sites. The structural characteristics recited in the present claims render them patentably distinct from claims 1-39 of the '056 patent.

The Examiner bases the present rejection on the grounds that the presently pending "species" claims would anticipate the "genus" claims of the '056 patent, presumably finding that this is a basis for establishing obviousness-type double patenting. Whether later issued species claims anticipate earlier issued genus claims is irrelevant to an obviousness-type double patenting analysis. The proper comparison for obviousness-type double patenting is the subject matter defined by the conflicting claims and whether the later claims are *obvious* in view of the earlier issued claims. A two-part inquiry is used to determine whether claims in the commonly owned patent render the claims in the pending patent application obvious. MPEP § 804. First, the conflicting claims are construed and their differences determined. *Id.* Second, a determination is made as to whether the differences between the claims render the subject matter defined by the claims of the patent application patentably distinct from the subject matter defined by the claims of the commonly owned patent. *Id.*

In reviewing pending claims 22-25 and 28-68 in view of claims 1-39 of the '056 patent, the conflicting claims should be construed, compared and their differences determined. For instance, claims 1-39 of the '056 patent instant claim 22 should be reviewed as a whole for the subject matter they define. Claims 22-25 and 28-68 of the instant application should be similarly reviewed. The differences between the claims of the '056 patent and claims 22-25 and 28-68 of the present application should then be identified and examined for whether they render the instant claims patentably distinct from claims 1-39 of the '056 patent. That is, do the host of conjugates defined by claims 1-39 of the '056 patent as a whole render the chemically defined conjugates defined by claims 22-25 and 28-68 obvious to a person of skill in the art? The claims from the '056 patent should not be reviewed for particular embodiments that happen to fall within the scope of, but are not suggested by the claims, even where such embodiments are described in the detailed description of the '056 patent.

The subject matter defined by claims 1-39 of the '056 patent does not suggest a conjugate where the valency platform molecule of the conjugate has specific structural and chemical features, such as those claimed in claims 22-25 and 28-68 of the present application. Claim 1 of the '056 patent does not suggest conjugates of a particular valency platform molecule and does not suggest conjugates where the valency platform molecule of the conjugates has the presently claimed features, such as branching groups, attachment sites at termini of the platform molecule and a defined valency. Rather, claim 1 of the '056 patent describes a set of conjugates without regard to the specific chemical and structural features of the valency platform molecule of the conjugate. The chemical and structural features of the conjugates presently claimed would not have been obvious from a claim reciting conjugates without regard to such features. Similarly, dependent claims 2-39 of the '056 patent do not suggest the chemically defined conjugates presently claimed. Accordingly, claims 22-25 and 28-68 are not obvious over claims 1-39 of the '056 patent and Applicants respectfully request withdrawal of the present rejection.

Further, domination, the situation whereby a genus claim is present in a commonly owned patent and a species claim is present in a later pending application is, according to the Federal Circuit, a "commonplace situation [and] is not, per se, doubling patenting . . ." *In re Kaplan*, 789 F.2d at 1577. The fact that an earlier issued genus claim may read on certain subject matter that is also within the scope of the later species claim provides no insight into whether the differences between the earlier genus claim and the later species claim are obvious. Similarly, the fact that a species claim may in the abstract 'anticipate' the genus claims provides no insight into whether the differences between the earlier genus claims and the later species claims are obvious. Although a species claim will generally render a genus claim obvious, a genus claim in an earlier issued patent, without more, will generally not render obvious the narrower subject matter of the species claim under the doctrine of obviousness type double patenting.

The present rejection is based in an incorrect rationale that later 'species' claims which could 'anticipate' earlier-issued claims form the basis for an obviousness-type double patenting rejection. This notion is clearly rejected by case law and the MPEP. Under the correct application of the law, claims 22-25 and 28-68 are not unpatentable over claims 1-39 of the '056 patent because

the structural features in the rejected claims render them patentably distinct from the claims of the '056 patent. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the obviousness double patenting rejection of claims 22-25 and 28-68.

**Common Ownership of U.S. Patent No. 6,060,056**

The subject matter of U.S. Patent 6,060,056 and the instant application were co-owned or subject to an assignment obligation to the Assignee of record in the instant application at the time the presently claimed invention was made.

The Examiner states, "A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004." Consideration of the December 10, 2004 date is not required in the present case. December 10, 2004 becomes relevant in the context of a reexamination proceeding to determine whether the 102(e) exception to 35 U.S.C. 103(a) applies. MPEP §§ 706.02(l)(1), 2161. However, the filing date of the present application, December 29, 2000, post-dates the November 29, 1999 enactment of 35 U.S.C. 103(c), which added the 102(e) exception to 35 U.S.C. 103(a). Thus, a commonly owned reference that qualifies only under 35 U.S.C. 102(e) will not preclude patentability of the instant claims under 35 U.S.C. § 103 where the subject matter of the reference and the claimed inventions were owned by or subject to an obligation of assignment to the same entity at the time the claimed invention was made.

An interference between the present application and the '056 patent is not appropriate because the '056 patent and the present application are commonly owned and, or in the alternative, the instant claims are patentably distinct from the claims of the '056 patent, as discussed above under the obviousness-type double patenting section.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.: 252312005706. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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